Clinical Study Protocol

Retrospective clinical evaluation of nano-hybrid-composite denture teeth SR Phonares II

Type of investigation:	Clinical investigation concerning medical devices
Categorisation:	Category according to Art 6 ClinO-MD: A1
Registration:	Registry at ClinicalTrials.gov of the U.S. National Library of Medicine (http://www.clinicaltrials.gov) The trial additionally registers in the supplementary federal database (Portal for clinical trials in Switzerland - SNCTP, https://www.kofam.ch/en/snctp-portal/) with its submission on BASEC. Furthermore, as soon as the new electronic system EUDAMED2 is operational, the clinical investigation will be retrospectively registered, if required.
Identifier:	LL 5267725
Principal Investigator and Sponsor, or Sponsor-Investigator:	Principal Investigator (PI): Dr. med. dent. Ronny Watzke Benderstrasse 2 9494 Schaan Fürstentum Liechtenstein Tel.: [redacted] Mail: [redacted] Sponsor: Ivoclar Vivadent AG Benderstrasse 2 9494 Schaan Fürstentum Liechtenstein
Sponsor representative (if the Sponsor is not located in Switzerland)	Patrik Oehri Senior Director Corporate Quality Management/PRRC Tel.: [redacted] Mail: [redacted]
Medical Device:	SR Phonares II (Ivoclar Vivadent AG) Article — UDI SR Phonares II Ant. 6er OS71 A2 — DIVO6448651 SR Phonares II Ant. 6er OS71 A3 — DIVO6448661 SR Phonares II Ant. 6er OS72 A3 — DIVO6448861 SR Phonares II Ant. 6er OB71 A3 — DIVO6450461

	SR Phonares II Ant. 6er OB72 A3	DIVO6450661
	SR Phonares II Ant. 6er OB73 A3	DIVO6450861
	SR Phonares II Ant. 6er OB73 A3.5	DIVO6450871
	SR Phonares II Ant. 6er UL50 A2	DIVO6451651
	SR Phonares II Ant. 6er UL51 A3	DIVO6451861
	SR Phonares II Ant. 6er UL51 A3.5	DIVO6451871
	SR Phonares II Ant. 6er UL52 A3	DIVO6452061
	SR Phonares II Ant. 6er UL53 A3	DIVO6452261
	SR Phonares II Typ 8er ONU3 A3	DIVO6453661
	SR Phonares II Typ 8er ONU5 A3	DIVO6453861
	SR Phonares II Typ 8er ONU5 A3.5	DIVO6453871
	SR Phonares II Typ 8er ONU6 A3	DIVO6454061
	SR Phonares II Typ 8er UNL3 A2	DIVO6454251
	SR Phonares II Typ 8er UNL5 A3	DIVO6454461
	SR Phonares II Typ 8er UNL5 A3.5	DIVO6454471
Version and Date:	Version 2.0, 19.09.2022	

Signature Page(s)

ID number of the investigation:	LL 5267725 Registry at ClinicalTrials.gov of the U.S. National Library of Medicine (http://www.clinicaltrials.gov): The trial additionally registers in the supplementary federal database (Portal for clinical trials in Switzerland - SNCTP, https://www.kofam.ch/en/snctp-portal/) with its submission on BASEC. Furthermore, as soon as the new electronic system EUDAMED2 is operational, the clinical investigation will be retrospectively registered, if required.
Title:	Retrospective clinical evaluation of nano-hybrid-composite denture teeth SR Phonares II

The Sponsor, the Principal Investigator and the Statistician have approved the CIP version 1.0 (dated 23.08.2022) and confirm hereby to conduct the investigation according to the CIP, the current version of the World Medical Association Declaration of Helsinki, ISO14155 norm, ICH-GCP as far as applicable, and the local legally applicable requirements.

Sponsor-Representative:

Patrik Oehri

Schaan, 19.09.2022

Place/Date

[redacted]

Signature

Principal Investigator:

Dr. med. dent. Ronny Watzke

Schaan, 20.09.2022

Place/Date

[redacted]

Signature

1. SYNOPSIS

Sponsor / Sponsor-Investigator	Ivoclar Vivadent AG
Title:	Retrospective clinical evaluation of nano-hybrid-composite denture teeth SR Phonares II
Short title / Investigation ID:	Retrospective clinical evaluation of SR Phonares II Investigation ID: LL 5267725
Clinical Investigation Plan, version and date:	Version 2.0, 19.09.2022
Registration:	Registry at ClinicalTrials.gov of the U.S. National Library of Medicine (http://www.clinicaltrials.gov): The trial additionally registers in the supplementary federal database (Portal for clinical trials in Switzerland - SNCTP, https://www.kofam.ch/en/snctp-portal/) with its submission on BASEC. Furthermore, as soon as the new electronic system EUDAMED2 is operational, the clinical investigation will be retrospectively registered, if required.
Category and its rationale:	Category A1 The medical device has conformity marking and will be used according to its instruction for use. The subjects are not subjected to any additional invasive or stressful procedures compared with those applied under normal conditions of use of the product.

Name of the MD, Unique Device Identification (UDI), name of the manufacturer	SR Phonares II Article — UDI SR Phonares II Ant. 6er OS71 A2 — DIVO6448651 SR Phonares II Ant. 6er OS71 A3 — DIVO6448661 SR Phonares II Ant. 6er OS72 A3 — DIVO6448861 SR Phonares II Ant. 6er OB71 A3 — DIVO6450461 SR Phonares II Ant. 6er OB72 A3 — DIVO6450661 SR Phonares II Ant. 6er OB73 A3 — DIVO6450861 SR Phonares II Ant. 6er OB73 A3.5 — DIVO6450871 SR Phonares II Ant. 6er UL50 A2 — DIVO6451651 SR Phonares II Ant. 6er UL51 A3 — DIVO6451861 SR Phonares II Ant. 6er UL51 A3.5 — DIVO6451871 SR Phonares II Ant. 6er UL52 A3 — DIVO6452061 SR Phonares II Ant. 6er UL53 A3 — DIVO6452261 SR Phonares II Typ 8er ONU3 A3 — DIVO6453661 SR Phonares II Typ 8er ONU5 A3 — DIVO6453861 SR Phonares II Typ 8er ONU5 A3.5 — DIVO6453871 SR Phonares II Typ 8er ONU6 A3 — DIVO6454061 SR Phonares II Typ 8er UNL3 A2 — DIVO6454251 SR Phonares II Typ 8er UNL5 A3 — DIVO6454461 SR Phonares II Typ 8er UNL5 A3.5 — DIVO6454471 Ivoclar Vivadent AG Benderer Strasse 2 9494 Schaan
Stage of development:	Post-market stage with CE marking
Background and rationale:	This retrospective study investigates the longevity of dentures with SR Phonares II teeth after a wearing period of more than 10 years.
Objective(s):	The primary objective is to assess the survival rate of dentures with SR Phonares II teeth after more than 10 years. The secondary objectives asses the quality of the dentures concerning aesthetic, functional and biological properties.
Outcome(s):	The primary outcome of the study is the survival rate of the dentures with the tested denture teeth. The secondary outcomes are all linked to the quality of the materials used (surface lustre, staining, plaque accumulation, color match, aesthetic anatomical form, fracture, marginal adaptation, occlusal contour, wear patients view, integrity of adjacent natural teeth, adjacent mucosa, oral health).
Design:	Retrospective evaluation

Inclusion / exclusion criteria:	Subjects fulfilling all inclusion criteria are eligible for the investigation: informed consent signed and understood by the subject, partial or full denture with SR Phonares II teeth, dentures delivered in the internal clinic between August 2010 and August 2012, to be able to visit the internal clinic (Exception: Patients with limited mobility are also included if another person can carry the dentures to the internal clinic of Ivoclar Vivadent AG for the examination.). The presence of any of the following exclusion criteria will lead to the exclusion of the subject: patient does not wear the dentures regularly, health status (physical and mental) does not allow participation.
Measurements and procedures:	The intraoral situation will be examined similar to a standard dental examination. The dentures are then removed, cleaned and examined extraoral. Pictures and an impression of the dentures are taken.
Intervention:	The examinations do not differ from standard dental examinations. Impressions of the back teeth of the dentures are taken extraoral and stone casts are poured. They are used for analysis of wear and microscopical analysis.
Control intervention (if applicable):	n.a.
Number of subjects with rationale:	22 patients that were supplied with dentures with SR Phonares II teeth (in total 43 dentures) in the internal clinic of Ivoclar Vivadent AG between August 2010 and August 2012.
Duration of the investigation:	6 months
Investigation schedule:	October 2022 First- subject –In (planned) March 2023 Last- subject –Out (planned)
Investigator(s):	Dr. med. dent. Ronny Watzke Benderertrasse 2 9494 Schaan Fürstentum Liechtenstein Tel.: [redacted] Mail: [redacted]
Investigational Site(s):	This is a single centre study. R&D Clinic Ivoclar Vivadent AG Benderertrasse 2 9494 Schaan Fürstentum Liechtenstein
Statistical considerations:	Since the study is retrospective with a small cohort and no control group, mainly descriptive statistical analysis will be performed. The obtained data, especially the survival rate will be discussed and compared with data from the literature. A minimal sample size of 41 dentures was calculated with absolute error (precision of 10% and and standard normal variate of 5% (type 1 error)).
Compliance statement:	This investigation will be conducted in compliance with the CIP, the current version of the Declaration of Helsinki, ISO14155, ICH-GCP (as far as applicable) as well as all national legal and regulatory requirements.

2. ABBREVIATIONS

AE	Adverse Event
ADE	Adverse Device Effect
ASADE	Anticipated Serious Adverse Device Effect
ASR	Annual Safety Report
CA	Competent Authority (e.g. Swissmedic)
CEC	Competent Ethics Committee
CIP	Clinical investigation plan
ClinO	Ordinance on Clinical Trials in Human Research *(in German KlinV, in French Oclin, in Italian OSRUm)*
ClinO-MD	Ordinance on Clinical Trials with Medical Devices *(in German: KlinV-Mep, in French: Oclin-Dim, in Italian: OSRUm-Dmed)*
CRF	Case Report Form (pCRF paper CRF; eCRF electronic CRF)
DD	Device Deficiency
DMC / DSMC	Data Monitoring Committee, Data Safety Monitoring Committee
Ho	Null hypothesis
H1	Alternative hypothesis
HRA	Federal Act on Research involving Human Beings *(in German: HFG, in French: LRH, in Italian: LRUm)*
IB	Investigator's Brochure
ICF	Informed Consent Form
ICH-GCP	International Council for Harmonisation – guidelines of Good Clinical Practice
IFU	Instruction For Use
ISF	Investigator Site File
ISO	International Organisation for Standardisation
ITT	Intention to treat
MedDO	Medical Devices Ordinance *(in German: MepV, in French: Odim, in Italian: Odmed)*
MD	Medical Device
MDR	Medical Device Regulation (EU) 2017/745 of 5 April 2017
PI	Principal Investigator
SADE	Serious Adverse Device Effect
SAE	Serious Adverse Event
SDV	Source Data Verification
SNCTP	Swiss National Clinical Trials Portal
SOP	Standard Operating Procedure
USADE	Unanticipated Serious Adverse Device Effect

3. SUMMARY OF THE REVISION HISTORY IN CASE OF AMENDMENTS

Version Nr, Version Date	Chapter	Description of change	Reason for the change

4. INVESTIGATION SCHEDULE

Investigation Periods	Patient information	Consent (ICF)	Recall
Visit	0	1	1
Time (day)	-3	0	0
Patient Information by phone	x		
Patient consent (ICF)		x	
Primary Variables			x
Secondary Variables			x
Dental radiograph			(x)
Adverse events			x
Device Deficiencies			x

(x) dental radiographs of a single tooth or dental implant will only be taken if necessary for medical reasons independent of the clinical trial.